

PROGRAM STANDARDS AND POLICIES

Breast and Cervical Cancer Control Program

2001-2002

Texas Department of Health

SECTION TWO: STANDARDS AND POLICIES

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Standard I: Women participating in the Program must meet eligibility guidelines.

- A. *Financial Eligibility Policy:* Providers must assure a woman meets financial eligibility requirements and is not enrolled in Medicare Part B. *Purpose:* To assure limited federal Program funds are used first for women who would otherwise not have access to screening and/or diagnostic tests and give the provider initial information on eligibility for other resources.

Requirements for Financial Eligibility Compliance

Provider must:

1. Develop forms or use current agency forms to determine financial eligibility for the Breast and Cervical Control Program. To meet the minimum requirements for eligibility under the Program, a woman must:
 - have an income at or below 200 percent of the federal poverty level; and be uninsured, OR
 - have an income at or below 200 percent of the federal poverty level; and be unable to pay her insurance deductible or co-payment; and not have or not be enrolled in Medicare Part B.
2. Apply for all other available sources of third party funding before submitting claims to the BCCCP for services rendered.
3. Provide BCCCP-funded services free-of-charge to eligible women.
4. Determine if the woman was ever served under the BCCCP.
5. Document special eligibility circumstances in the client's record (e.g. why a woman who has Medicaid or is eligible for Medicare, Part B is seen under the BCCCP).

Guidelines/Protocols

- Public Law 105-340
- Income eligibility guidelines, 2001

Data Sources/Evaluative Criteria

- Medical records, eligibility forms; BCCCP screening and/or diagnostic forms; TDH State Office database/records audits

Standard I: Women participating in the Program must meet eligibility guidelines.

- B. *Classification Eligibility Policy*: Providers must assure a woman meets Program screening guidelines. *Purpose*: To assure that limited Program funds are used to provide services to women who are at the highest risk for breast or cervical cancer and the State Program complies with federal policy.

Requirements for Classification Compliance

1. Breast Cancer Screening Services

Providers must:

- provide at least 75 percent of Program-funded mammograms to women age 50-64; and
- assure no more than 25 percent of the Program-funded mammograms are provided to women age 40-49.

2. Breast Cancer Diagnostic Services

Women of any age can be enrolled in the Program for diagnostic assessment if she is:

- symptomatic, **AND**
- has an abnormal clinical breast examination, **AND/OR**
- abnormal mammogram

3. Cervical Cancer Screening Services

To be eligible for cervical cancer screening services, a woman must meet financial eligibility and:

- be age 18 or older; **OR**
- have had a hysterectomy due to cervical cancer or neoplasia; **OR**
- have had a recent abnormal Pap test result.

Providers must:

- provide at least 20 percent of program-funded Pap tests to women never or rarely screened (no Pap test within the last 5 years) as documented in the BCCCP database; **AND**
- assure that 75 percent of the women that have had three consecutive normal annual program-funded Pap tests within a 5 year period (as documented in the BCCCP database) do not receive a fourth annual Pap test. Once there is documentation of three normal/benign results within a five year period, program funds may be used to reimburse for Pap tests once every three years.

4. Cervical Cancer Diagnostic Services

Women age 18 and older may be enrolled in the Program for diagnostic assessment provided there is:

- documentation of two abnormal Pap results of Atypical Squamous Cells of Undetermined Significance (ASCUS) or Low-Grade Squamous Intra-epithelial Lesion (LSIL) which are 3-6 months apart, **OR**
- one abnormal Pap result of High-Grade Squamous Intra-epithelial Lesion (HSIL) or Atypical Glandular Cells of Undetermined Significance (AGUS).

Guidelines/Protocols

- CDC Program guidelines, Public Law 105-340
- BCCCP, Breast Health: A Guide for Screening Programs
- BCCCP, Cervical Health: A Guide for Screening Programs
- Income eligibility guidelines, 2001
- BCCCP Database

Data Sources/Evaluative Criteria

- Medical records, eligibility forms; screening and/or diagnostic forms; TDH State office database/records audits

Standard II: Women will receive breast and cervical cancer screening services according to Centers for Disease Control and Prevention (CDC) guidelines.

- A. *Breast Cancer Screening Policy:* Providers must assure that breast cancer screening meets standards of care. *Purpose:* To assure eligible women receive quality breast cancer screening.

Requirements for Breast Cancer Screening Compliance

Only women age 50-64 may receive Breast and Cervical Cancer Control Program-funded breast cancer screening services (with the exception of previous BCCCP breast cancer screening clients, age 40-49 screened prior to October 1, 1994). No woman age 40 or older and eligible for Medicare, Part B, may receive program-funded services.

Providers must:

1. offer breast cancer screening free-of-charge to eligible women;
2. provide the type, quantity, and quality of breast cancer services agreed upon in the signed contract or agreement with BCCCP;
3. obtain a written informed consent for services, signed by each woman participating in the BCCCP;
4. obtain a signed contract or agreement for any subcontracted service funded by the BCCCP and assure that subcontractors meet Program requirements;
5. provide a complete breast cancer screening, which includes both a clinical breast examination and a mammogram and adhere to the definition of a screening cycle;
6. provide documentation of clinical breast examination and of mammography results;
7. complete a screening form for each woman receiving breast cancer screening and document all services, results, and client notification;
8. provide and document individualized information to each woman about breast cancer including oral and written information in the woman's primary language. Educational materials must be presented in a manner that is consistent with the woman's age and educational background;
9. assure the woman receives a mammogram within 60 days following her clinical breast examination (if the clinical breast examination was normal);*
10. provide breast cancer screening services by qualified staff; and

11. assure the mammography provider is certified by the Texas Department of Health and the Food and Drug Administration.

Guidelines/Protocols

- CDC Program guidelines, Public Law 105-340
- BCCCP, Breast Health: A Guide for Screening Programs

Data Sources/Evaluative Criteria

- Medical records, data forms, BCCCP State office database

Standard II: Women will receive breast and cervical cancer screening services according to Centers for Disease Control and Prevention (CDC) guidelines.

B. *Cervical Cancer Screening Policy:* Providers must assure that cervical cancer screening must meet standards of care. *Purpose:* To assure eligible women receive high quality cervical cancer screening.

Requirements for Cervical Cancer Screening Compliance

Providers must:

1. offer Breast and Cervical Cancer Control Program-funded cervical cancer screening free-of-charge to women age 18 or older;
2. provide the type, quantity, and quality of services agreed upon in the signed contract or agreement with BCCCP;
3. obtain a written informed consent for services for each enrolled woman;
4. obtain a contract or agreement for any subcontracted service funded by the BCCCP and assure subcontractors meet Program requirements;
5. provide cervical cancer screening services according to CDC guidelines including a pelvic examination and a Pap test; in addition, provide a clinical breast examination to all women receiving cervical cancer screening;
6. provide documentation of the pelvic examination, clinical breast examination and Pap test results;
7. initiate a screening form for each woman receiving cervical screening services and document services in the client's record;
8. provide and document individualized information to each woman about cervical cancer including oral and written information in the woman's primary language. Educational materials should be presented in a manner that is consistent with the woman's age and educational background;
9. provide cervical cancer screening by qualified staff;
10. assure the cytology laboratory interpreting Program funded Pap tests is accredited and certified according to state and federal law; and

11. charge only “satisfactory” Pap tests to the BCCCP.

Guidelines/Protocols

- Title VI of the Civil Rights Act of 1964, Section 601
- CDC Program guidelines; Public Law 105-340
- Breast and Cervical Cancer Control Program, Cervical Health: A Guide for Screening Programs
- M.D. Anderson, Cervical Cancer Syllabus

Data Sources/Evaluative Criteria

- Medical records, data collection forms, BCCCP database

STANDARD III: Enrolled women will be rescreened at appropriate intervals.

Rescreening Policy: Providers must assure that Program-eligible women receive appropriate rescreening services. *Purpose:* To assure that each woman receives routine screening services at appropriate time intervals in order to detect breast cancer at an early stage.

Requirements for Rescreening Compliance

Providers must determine each previously enrolled woman's continued eligibility for Program services. A woman eligible for rescreening is a woman who received a Breast and Cervical Cancer Program-funded breast cancer screening during the previous 12-month budget period, meets Program eligibility requirements and is clinically eligible for rescreening.

Note: A woman may not be clinically eligible for rescreening during a particular rescreening interval if she is receiving treatment or follow-up for a previous abnormality. Her next screening date should be determined by the clinician.

Providers must:

1. rescreen at least the minimum required percentage of women from the priority population during each 12-month period;
2. remain in compliance with the Program requirement that no less than 75% of all mammograms funded in a budget period are provided to women age 50-64;
3. provide information on the need for regular screening to every woman during her regular visit (must include written instruction);
4. implement a recall system to remind a woman of her next regular screening; and
5. assess and document a woman's eligibility.

Guidelines/Protocols

- CDC Program guidelines, Public Law 105-340
- BCCCP Rescreening: A Guide for Screening Programs
- Case Management: A Guide for Screening Programs
- Program Training Modules: Screening

Data Sources/Evaluative Criteria

- Medical records, data collection forms; BCCCP database
- Program data including number and characteristics of women, eligibility status, final disposition or diagnosis, and quarterly reports.

STANDARD IV: Enrolled women will be followed through screening, diagnosis, and initiation of treatment.

Follow-up and Case Management Policy: Providers must assure appropriate care for all women requiring follow-up. Case management services must be implemented following the receipt of an abnormal screening or diagnostic result. The proportion of clients who are lost to follow-up will be less than three percent of all abnormal screening results. *Purpose:* To assure that each woman who has an abnormal screening or diagnostic result receives appropriate services.

Requirements for Follow-up and Case Management Compliance

Case management services begin with the receipt of abnormal screening results. Services end when the client is found to be without cancer, or if cancer is detected, with initiation of treatment, or when the client refuses or is lost to follow-up. Clients will be offered rescreening services according to current rescreening policy. If extenuating circumstances require case management beyond this scope, oversight will be sought from the state office staff.

1. Providers must develop appropriate resources for their enrolled clients and:
 - develop a protocol for making referrals; and
 - notify the state office when resources are not available for individual clients.
2. Providers must assure the case management functions of assessment, planning, and monitoring occur with each enrolled woman, at a minimum:
 - all clients with an abnormal result receive a comprehensive needs assessment within 30 days of receipt of the result or prior to the initiation of the first diagnostic service. **The state office requires that the content of the Breast and Cervical Cancer Control Program comprehensive needs assessment form be used; however the format can be modified to meet an agency's tracking needs;**
 - clients must sign a consent for case management, which contains assurances that confidentiality will be maintained;
 - timeliness of client notification is dictated by the severity of the results. Attempts to contact a client following receipt of an abnormal **screening** are made as soon as possible but no later than five working days. Attempts to contact a client must be made, as soon as possible but no later than two working days following the receipt of an abnormal **diagnostic** result. Such attempts can be made by office visit, telephone, home visit or by mail. Programs should assess whether the attempt is likely to result in successful contact with the client. Attempts to contact the client must be written or presented orally (when appropriate) in the client's primary language, including appropriate provisions for the visually and hearing impaired;
 - before considering a client lost to follow-up, there must be at least three (3) separate attempts to contact her with the last by certified mail;
 - the case management plan includes the client's participation. The agency or individual responsible for meeting the needs identified through screening and

assessment will be listed on the plan. Time frames and the interventions should be appropriate, responding to the severity of the results and the client need. Following the receipt of the abnormal result, client contact will be based according to the severity of results. Severity of results should also dictate the action objective identified within the plan. **State office recommends the use of the BCCCP service agreement plan; and**

- within one month after the client and case manager complete the case management plan, the case manager must follow-up and document that the service was actually implemented i.e., monitoring of the plan. Ongoing reassessment of the client's needs must occur. As new problems are noted, they are recorded on the plan and the accompanying services and time frames are indicated.
3. Providers must complete adequate and timely written documentation of follow-up for each enrolled woman including:
- all contacts and attempts to contact the client regarding the need for follow-up must be documented in the client record. Copies of any written correspondence sent to the client should be filed in the client's medical record;
 - all of the diagnostic or treatment services that took place with the results. Results must be obtained from the appropriate facility or private physician and secured in the client record;
 - the completed diagnostic data form for each woman requiring diagnostic services and submitted to TDH;
 - the case management needs assessment, plan, and monitoring activities, which must be included in the client's individual record;
 - changes in the case management plan. Often, the plan fails when the client's barriers to obtaining diagnostic services or treatment have been changed. When this occurs, the plan is modified to reflect new problems and planned services, then documented in the client's record;
 - documentation to the State office with data forms for clients who are designated as lost to follow up. A client is considered lost to follow up only when she cannot be located. Documentation of attempts to contact including the last attempt noted by certified mail must be in the client record;
 - informed refusal should be obtained in writing from the client if the client fails to keep appointments according to a prior agreement. Informed refusal should contain any procedures refused, and why they were recommended and the risks of not following through with the recommendations. The reason for refusal should be noted in the record. Before closing the client record as a refusal, a thorough review of the client's plan and the client's agreement and participation should be made; and
 - a release of information must be signed by the client in order to obtain diagnostic, treatment or staging information from private physicians, or tertiary care providers. An agency that discontinues BCCCP services due to termination of contractual agreement with TDH, must assure clients with abnormal screening or diagnostic results receive continues follow-up and case management. Diagnostic forms are to be completed and submitted by the originating screening contractor.

4. Case management should always promote self-sufficiency through education and support.
5. Case management plans and objectives should be support the following case management indicators.
 - A shortened interval between screening, diagnosis and treatment.
 - A reduction in the lost to follow-up or refusals.
 - The initiation of treatment within 30 days of the initial abnormal result.
6. Programs will have a plan for rescreening clients through tracking and reminder systems as outlined in their agency-specific plans.
7. Staff designated as regional case management coordinators will act in liaison with TDH staff for quality assurance in accordance with established job descriptions.
8. Programs must incorporate a system to assess client satisfaction of access to and quality of referral services, as well as the quality of case management plans.
9. Staff performing case management functions of assessment, planning and monitoring must complete a designated training program sanctioned or developed by TDH.

Guidelines/Protocols

- Public Law 105-340
- BCCCP, Case Management: A Guide for Screening Programs
- BCCCP, Breast Health: A Guide for Screening Programs
- BCCCP, Cervical Health: A Guide for Screening Programs

Data Sources/Evaluative Criteria

- Client records, provider tickler system, and computerized or manual tracking system, database
- Medical record audits; BCCCP data files
- Date of clinical breast examination, date of mammography, or cervical screening

Standard V: The public will be informed about breast and cervical cancer including the availability and accessibility of services.

- A. *Client Education Policy:* Providers must adequately inform women receiving Program services about breast and cervical cancer. *Purpose:* To assure that each woman served under the BCCCP has appropriate information on breast and cervical cancer in order to participate in her individualized care program.

Requirements for Client Education

1. The Provider must present and document breast and cervical cancer information to every woman who receives Program services. The following information must be explained verbally to each woman in her primary language and may be supplemented with printed or audio-visual materials in the woman's primary language:
 - a description of cancer;
 - explain factors that make it more likely that a person will get breast cancer;
 - the importance of getting screened at regular intervals;
 - symptoms to look for;
 - the medical procedures which the woman will undergo as part of her current check-up;
 - steps a woman must take to complete her current check-up;
 - describe possible results of the medical procedures;
 - a reminder to the woman of when she should schedule her next regular appointment;
 - information to the woman that her eligibility to receive services at no charge can change from year to year;
 - an explanation that returning for regular visits is a shared responsibility; and
 - a telephone number to call with questions and to make her next appointment;
2. Every client, including those with Limited English Proficiency (LEP) must be given information about, and be able to understand, the services that can be provided by the health care provider to address her situation and must be able to communicate her situation to the health care provider. A health care provider cannot require a client to use friends or family members as interpreters. A health care provider must ensure that only persons who are competent to provide interpreter services work with the client.

Guidelines/Protocols

- BCCCP, Breast Health: A Guide for Screening Programs
- BCCCP, Cervical Health: A Guide for Screening Programs
- Program Training Modules: Health Promotion

Data Sources/Evaluative Criteria

- Written policies and procedures
- Documentation of client education in client medical record
- Supply of educational materials

Standard V: The public will be informed about breast and cervical cancer including the availability and accessibility of services.

B. Limited English Proficiency Policy (LEP): Providers will give appropriate oral and written information on breast and cervical cancer to persons with LEP. *Purpose:* To ensure that persons with LEP receive information about, and are able to understand the scope of service delivery available to them in their primary language.

Requirements for LEP Compliance

Providers must take reasonable steps to provide services and information in appropriate languages in order to ensure that a woman with LEP is effectively informed and able to participate in her individualized care program.

Providers must:

1. have a procedure for identifying the language needs of clients;
2. develop written policies and procedures regarding interpreter services;
3. disseminate interpreter policies and procedures to staff and ensure staff awareness of these policies and procedures and of their Title VI obligation to persons with LEP;
4. furnish oral and written information in the individual's primary language;
5. have ready access to and provide services of proficient interpreters in a timely manner during hours of operation; and
6. ensure that oral communication given is relayed through an interpreter oriented in the ethics of interpreting, proficient in both English and the other language, and sufficiently familiar in both languages of any specialized terms peculiar to a Program activity. Providers cannot require a person of LEP to use friends or family members as interpreter. However, a family member or friend may be used as an interpreter if this approach is requested by the individual and this does not compromise the effectiveness of the service or violate confidentiality of the client.

Guidelines/Protocols

- Title VI of the Civil Rights Act of 1964, Section 601

Data Sources/Evaluative Criteria

- Available educational materials
- Individual client documentation in clinical records

Standard V: The public will be informed about breast and cervical cancer including the availability and accessibility of services.

C. *Public Information Policy:* Providers must inform the public about the availability and accessibility of program services. *Purpose:* To bring about positive change in knowledge and behavior related to breast and cervical cancer.

Requirements for Public Information

A provider must conduct outreach activities if less than 75 percent of all mammograms are provided to women age 50-64, or the projected number of women to be screened is not reached. Providers must:

1. Develop and implement strategies to enroll women into the program.
 - identify a priority population to receive information;
 - identify and develop relationships with other programs within the provider agency to reach eligible women in the priority population; and
 - identify and develop relationships with other organizations to reach eligible women in the priority population.
2. Provide information to eligible women in the woman's primary language.
3. Provide access to information that is culturally sensitive, linguistically appropriate and includes the visually and hearing impaired.
4. Document and maintain records of outreach activities to enroll women in the program.

Guidelines/Protocols

- TDH BCCCP Manual of Operations, Public Information References
- Title VI of the Civil Rights Act of 1964, Section 601
- Americans with Disabilities Act

Data Sources/Evaluative Criteria

- List of persons responsible for coordinating outreach and public information activities
- Written policies and procedures
- Documentation of collaboration with other programs and organizations to enroll eligible women in the priority population
- Availability of educational materials which include telephone numbers and/or address of health provider

Standard VI: Women will receive breast and cervical cancer examinations from qualified staff who are proficient in the delivery of clinical services.

Professional Education Policy: Providers will give high quality services. *Purpose:* To assure women are screened at appropriate intervals, screening tests are performed optimally, and women with abnormal test results receive appropriate diagnostic follow-up and treatment.

Requirements for Professional Education

1. New agency staff must be oriented to the Breast and Cervical Cancer Control Program. The BCCCP training modules should be used to orient new agency staff on Program policies, standards, requirements, and recommendations to conduct breast and cervical cancer screening activities.
2. Providers must assure that:
 - breast and pelvic examinations will be performed by physicians, physician's assistants, nurse practitioners, certified nurse midwives, and registered nurses who have had specialized training by a recognized program beyond nursing school;
 - staff are adequately trained to perform clinical breast examinations, pelvic examinations, and Pap tests;
 - procedures follow current medically acceptable methods for breast and pelvic examinations and specimen collection;
 - clinical breast examination procedures must contain all essential components as referred in the BCCCP Breast Health: A Guide for Screening Programs; and
 - clinical pelvic examination and Pap test procedures contain all essential components as in referred in the BCCCP Cervical Health: A Guide for Screening Programs.

Guidelines/Protocols

- ACS, Byrd B.F. (1985), "Standard Clinical Breast Exam"
- M.D. Anderson Cancer Center, "Procedure for Breast Assessment"
- BCCCP, Breast Health: A Guide for Screening Programs and Cervical Health: A Guide for Screening Programs

Data Sources/Evaluative Criteria

- Medical records, staff credentials and documentation of training, policy/procedure manuals
- On-site reviews of service delivery, review of materials

Standard VII: Women will receive screening and diagnostic services from facilities that meet Program requirements.

A. *Quality Assurance Policy for Mammography:* Providers must assure mammography services are in compliance with state and federal laws.

Purpose: To assure that uniform standards for quality assurance are met in order for mammography to be most effective in detecting breast cancer.

Requirements for Mammography Quality Assurance

All mammography facilities providing services to the Program must:

- possess a valid Certificate of Mammography Systems from the Texas Department of Health Bureau of Radiation Control for each mammography unit, and
- possess a valid certificate from the United States Food and Drug Administration certifying compliance with the Federal Mammography Quality Reauthorization Act of 1998, 42 USC, §263b and provisions set out as a note under §263b.

Guidelines/Protocols

- Mammography Quality Reauthorization Act of 1998 (MQRA)
- CDC Program Guidelines; Public Law 105-340
- BCCCP, Breast Health: A Guide for Screening Programs

Data Sources/Evaluative Criteria

- Evidence of valid MQRA certification issued by the FDA
- Evidence of valid Certification of Mammography Systems issued by TDH
- Mammography reports

Standard VII: Women will receive screening and diagnostic services from facilities that meet Program requirements.

- B. *Cervical Cytology Policy:* Assure that cytology laboratories providing services to the Program are in compliance with all applicable laws, regulations and program requirements. *Purpose:* To assure that uniform standards of quality assurance are met in order to improve the effectiveness of cervical screening.

Requirements for Cytology Quality Assurance

1. Providers subcontracting for screening and diagnostic cytology services must have current documentation that the subcontractor for cytology meets all quality assurance standards required by the Breast and Cervical Cancer Control Program as established under state and federal laws.
2. All cytology laboratories providing services to the Program must:
 - possess a current, unrevoked or unsuspended Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) registration certificate issued by the U. S. Department of Health and Human Services (DHHS);
 - use the Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses;
 - possess a current copy of the Health Care Financing Administration Clinical Laboratory Application (HCFA-116) indicating that the cytology provider has applied for certification in cytology services;
 - be accredited by a HCFA-approved accrediting organization, or be certified by the Texas Department of Health (TDH) as in compliance with the Clinical Laboratory Improvement Amendments of 1988, 42 USC §263a; and,
 - report abnormal results (CIN III or greater) to the provider within 24 hours.

Guidelines/Protocols

- CLIA '88
- CDC Guidelines for Quality Assurance for Cervical Cytology and Program requirements for quality assurance related to cervical cytology
- BCCCP, Cervical Health: A Guide for Screening Programs

Data Sources/Evaluative Criteria

- CLIA registration certificate
- Documentation of accreditation or TDH certification, with certification in cytology
- Inspection reports from an accrediting organization or TDH
- Laboratory performance records

Standard VIII: Demographic, service delivery, and outcome data will be collected on each client.

A. *Policy on Collection of Data:* Providers must collect and report minimum data elements for every woman who receives Program services. *Purpose:* To assure that the priority population is served and that timely and appropriate services are provided to women.

Requirements for Collection of Data

1. New agency staff must be oriented to Breast and Cervical Cancer Control Program data reporting procedures.
2. BCCCP providers must track clients through the service delivery system.
3. Providers must use BCCCP data collection forms and:
 - assure each woman has a unique identifier number;
 - make monthly submissions of data collection forms;
 - make timely corrections to data collection forms as requested by State office staff;
 - update demographic and other information on the data collection forms or in the BCCCP database as indicated; and
 - participate in training opportunities on the use of BCCCP data collection requirements.

Guidelines/Protocols

- Public Law 105-340
- BCCCP Data Collection Guide
- Program Training Module: Data

Data Sources/Evaluative Criteria

- Medical records; screening/diagnostic data forms; BCCCP database

Standard VIII: Demographic, service delivery, and outcome data will be collected on each client provided services.

B. *Policy on Staging of Cancers:* Providers must collect and report the stage of disease for all confirmed diagnoses of breast cancer and invasive cervical cancer. *Purpose:* Information on the state of each diagnosed cancer is required to evaluate the Program's effectiveness in reducing breast and cervical cancer mortality.

Requirements for Staging of Cancers

1. Providers must contact hospitals and other treatment facilities including private physicians if the client was originally enrolled in the BCCCP to obtain stage of disease information for cancer diagnoses. Providers also may contact the TDH Cancer Registry for information.
2. Providers must collect the actual stage of disease from tertiary care facilities. Providers must submit a tumor node metastasis (TNM) form signed and dated by a physician or certified Tumor Registrar; or copies of the pathology report and the operative report.
3. Stage of disease must be reported using the Tumor, Node, Metastasis (TNM) classification system as developed by the American Joint Committee on Cancer. Clinical or histological staging information should be available.
4. In the event that an initial reported diagnosis of cancer turns out to be benign, the provider's records must reflect the new information and a revised diagnostic form must be submitted.
5. The stage of disease must be reported within sixty (60) days of the date the cancer diagnosis was made, as reported in the data collection form submitted to Breast and Cervical Cancer Control Program.

Guidelines/Protocols

- Public Law 105-340
- Program Training Module: Data
- BCCCP Data Collection Guide

Data Sources/Evaluative Criteria

- BCCCP databases
- Staging reports
- Medical records

Standard VIII: Demographic, service delivery, and outcome data will be collected on each client provided services.

C. *Policy on Use of Reporting Terminology:* Providers must assure use of required reporting terminology for mammography and cytology services. *Purpose:* To assure consistent interpretation of results by primary practitioners.

Requirements for Use of Reporting Terminology

Mammography Reports:

1. Facilities must prepare a written report of the results of each mammography examination. This report must include the following:
 - The name of the client and an additional client identifier;
 - The name of the physician who interpreted the mammogram;
 - An overall final assessment of findings, classified in one of the following categories:
 - * Negative
 - * Benign
 - * Probably benign- Finding has a high probability of being benign.
 - * Suspicious- Finding lacks all the characteristic morphology of breast cancer but indicates a definite probability of being malignant.
 - * Highly suggestive of malignancy
 - * Incomplete: need additional imaging evaluation- This category should be assigned in cases where no final assessment category can be assigned due to an incomplete imaging work up; and
 - The recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider must be addressed in the report to the extent possible, even if the assessment is negative or benign.
2. In addition to the overall final assessment, the following designations may be recorded on Breast and Cervical Cancer Control Program data collection forms:
 - Unsatisfactory, film could not be interpreted
 - Results Unknown (*performed elsewhere*)

Cytology Reports:

The Bethesda System for Reporting Cervical/Vaginal Diagnoses must be used for reporting cytology results. The three components of a cytology report using the Bethesda system are:

- Statement of adequacy of the specimen
- General categorization of the diagnosis:
 - *Within Normal Limits
 - *Benign cellular changes
 - *Epithelial cell abnormality
- Descriptive diagnosis:
 - *Infection/Inflammation/Reactive changes
 - *Atypical Squamous Cells of Undetermined Significance (ASCUS)
 - *Low Grade SIL (LGSIL)
 - *High Grade SIL (HGSIL)
 - *Squamous Cell Carcinoma
 - *Other (specify) i.e.,
 - AGUS (Atypical glandular cells of undetermined significance)
 - Adenocarcinoma
 - Atrophy
 - IUD
 - Radiation

Guidelines/Protocols

- Mammography Quality Reauthorization Act of 1998
- Bethesda System for Reporting Cervical/Vaginal Cytological Diagnoses, 1994
- CDC Program Guidelines

Data Source/Evaluative Criteria

- Medical records; screening/diagnostic data forms; BCCCP database

Standard VIII: Demographic, service delivery, and outcome data will be collected on each client.

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| D. <i>Policy on Confidentiality:</i> Providers will observe confidentiality guidelines in the use of client information. <i>Purpose:</i> To assure that all providers implement adequate safeguards for the individual's right to privacy. |
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Requirements for Compliance with Confidentiality

1. A client must be advised that screening, follow-up, diagnostic, and treatment information must be reported to the Texas Department of Health and Centers for Disease Control and Prevention.
2. The responsibility for the maintenance of confidentiality remains with the provider. Maintenance of confidentiality of identifiable information held by the providers extends beyond the medical records and program data forms to include interview records, records from other agencies, clients lists, death certificates, and other documents with identifiable client information.
3. Providers must obtain a signed medical release form from each client when requesting information from outside sources.
4. The provider must establish and follow agency guidelines outlining the preservation of confidentiality in connection with or during the process of collection, storage, use and transmission of identifiable Breast and Cervical Cancer Control Program information. Such guidelines should also cover releasing information to health care agencies, family members and law offices.
5. The provider must maintain the same standards of confidentiality in handling identifiable information as applies to the doctor-client relationship; this obligation extends indefinitely.
6. Guidelines for the maintenance of confidentiality apply not only to the storage of identifiable information on computers, but also to the storage of such data in the form of paper records, microfilm, microfiche, and magnetic media, and their transport or transmission by Program personnel in any of these formats.
7. When disclosing information, the provider should note that there are certain situations that may allow disclosure without prior written permission. These situations are: medical emergencies, reporting of child, spousal or elderly abuse, and documents that are subpoenaed.

Guidelines/Protocols

- International Association of Cancer Registrars

Data Source/Evaluative Criteria

- Medical records; screening/diagnostic data forms; BCCCP database

Standard IX: Reimbursement for Program Services must meet Program and Texas Department of Health requirements.

Reimbursement Policy: Providers will submit a voucher for reimbursement of allowable expenses on a monthly basis. *Purpose:* To allow local providers and the State office to monitor Breast and Cervical Cancer Control Program expenditures. To provide the State Office with a method to reimburse the provider for allowable expenditures under the BCCCP.

Requirements for Reimbursement

1. New staff must be oriented to BCCCP reimbursement requirements and procedures.
2. Claims for reimbursement must be made on the State of Texas Purchase Voucher (Form B-13) or the Interagency Transaction Voucher (ITV Form B-17) for State agencies.
3. Providers will submit State of Texas Purchase Vouchers (Form B-13) or ITV (B-17) directly to Grants Management.
4. Purchase vouchers must be submitted within **30** days following the end of the month covered by the reimbursement request.
5. All final claims for reimbursement must be submitted within **90** days following the end of the contract period.
6. Providers must have payments direct deposited (Government Code Section 403.016(C)).
7. A summary billing form (SUM) and data collection forms (D-19 and/or D-23, D-24) **must** be filled out (listing services provided for by CD number, CPT code(s), date of service and amount) and attached to each completed voucher for payment.
8. Providers must assure that each service billed is a complete service.

Guidelines/Protocols

- Grants Management Division, TDH
- BCCCP Billing instructions

Data Source/Evaluative Criteria

- Screening/diagnostic data forms; BCCCP database, voucher, SUM form

Standard X: Quality Assurance activities will be conducted.

Quality Assurance Policy: Providers must monitor Program activities on a regular basis.

Purpose: To assure that women screened under the Program receive quality service and to assist the State office in making funding decisions.

Requirements for Quality Assurance Activities

Providers must:

1. implement an internal quality assurance program to assure compliance with Breast and Cervical Cancer Control Program standards, guidelines, and rules as well as applicable Federal and State laws;
2. submit all required program reports;
3. respond in writing to on-site evaluations as required by the TDH Quality Assurance Division; and
4. provide appropriate Texas Department of Health staff access to records and assistance to the staff during technical assistance and on-site visits.

Guidelines/Protocols

- Public Law Act 105-340
- TDH, Community Health Nursing, Quality Care: Client Services Standards for Public Health and Community Clinics, June 1997

Data Source/Evaluative Criteria

- Contracts or agreements related to the Program
- Report of abnormal results generated by TDH database
- Laboratory reports on quality of cervical cytology submissions
- Staff credentials, Personnel policies
- Random chart audit/tickler system
- Manual of Operations
- Agency grant requests and reimbursement requests submitted to TDH/BCCCP
- Contractor performance monitoring review conducted by TDH staff, technical assistance visits